

December 3, 2021

To: The Office of Attorney General of Vermont

Via Email: AGO.highcostprescriptiondrugs@vermont.gov

Re: Meitheal Pharmaceuticals, Inc. New Drug Report – Generic Isosulfan Blue Injection 1%

To whom it may concern:

On November 5, 2021, and in accordance with the requirements set forth in the 18 V.S.A. § 4637 (b), Meitheal Pharmaceuticals, Inc. submitted a New Drug Notice on generic Isosulfan Blue Injection 1%.

Product Name and Description	NDC Number	WAC Price	Effective Date
Isosulfan Blue Injection 1% 50mg 5mL (10mg/mL) SD Vial	71288080506	\$800.00	11/03/2021

Meitheal Pharmaceuticals, Inc. now provides the following additional information pursuant to 18 V.S.A. § 4637 (c):

Marketing and Pricing Plans Used in Launch: Meitheal markets generic isosulfan blue injection 1% as a therapeutic equivalent to the innovator (brand) drug in the US. As such, Meitheal relies on the safety and efficacy findings of the FDA with respect to the innovator drug. Meitheal primarily markets to group purchasing organizations (GPOs), Integrated Delivery Networks (IDNs), and hospital/alternate site (own use) customers based solely on price and availability and therefore does not engage in direct-to-consumer, direct-to-physician, or prescriber marketing. Meitheal does not market based on any aspects of the drug itself, nor does Meitheal aim to treat a certain number of patients. Rather, Meitheal evaluates the size of the total market for a particular drug and strives to achieve a certain market share for that product. The target users for isosulfan blue are large cancer centers, teaching hospitals and cancer clinics.

Isosulfan blue injection 1% is used as an aid (or adjunct) in a procedure called lymphography (medical imaging procedure) to test how well the lymphatic system is working in certain parts of the body. It is used to find lymphedema, chyluria, chylous ascites, chylothorax, and cancer of the lymph nodes. Isosulfan blue is a dye made in the laboratory that helps identify the sentinel lymph node (the first lymph node that cancer spreads to from a primary tumor). Meitheal does not track the number of patients that are prescribed isosulfan blue, which is an adjunct to lymphography. Based on IMS data, Meitheal estimates that there are 80,000 units sold in the US each year.

Estimated Volume of Patients: Because this drug is a diagnostic, it is difficult to determine how many patients may be prescribed this drug. There are 80,000 units sold each year in the US based on IMS data.

Breakthrough Therapy Designation or Priority Review: Neither. The product was not granted priority review and did not receive a breakthrough therapy designation from the FDA.

Date and Price of Acquisition: Not applicable. This product was not the result of an acquisition.

Thank you for your consideration.

Sincerely,

Jean Allen
Senior Director, Contract Marketing
Meitheal Pharmaceuticals, Inc.